

NONPRESCRIPTION DRUGS
ADVISORY COMMITTEE AND
ARTHRITIS ADVISORY
COMMITTEE

JULY 20, 1999

NDA 21070

AGENDA

Proposed Agenda: Tuesday, July 20, 1999
Joint Meeting: Nonprescription Drugs and Arthritis Advisory Committees

Food and Drug Administration
Holiday Inn, Gaithersburg, Maryland

8:30 Call to Order, Introductions

Eric P. Brass, M. D., Ph.D., Chair, NDAC, Acting Committee Chair

Conflict of Interest Statement

Sandra Titus, Ph.D., Executive Secretary, NDAC

Welcome

John Hyde, M.D., Ph.D., Acting Deputy Director of Anti-Inflammatory, Analgesics and Ophthalmic Drug Products (DAAO)

Issue: Consideration of NDA 21-070, Flexeril 5mg (cyclobenzaprine HCL) Merck

8:45 FDA Presentations

Background and Efficacy

James Witter, M.D., Ph.D., Medical Officer, DAAO

Neurologic Impact

Paul Andreason, M.D., Medical Officer, Division of Neuropharmacological Drug Products

Abuse Potential

Michael Klein, Ph.D., Senior Interdisciplinary Scientist, Special Division of Controlled Substance

Safety

Rosemarie Neuner, M.D., MPH, Medical Officer, Division of Over-the-Counter (OTC)

Label Comprehension

Kathryn Aikin, Ph.D., Social Science Analyst, DDMAC

10:00 Break

10:15 Merck Presentations

Introduction

Edwin Hemwall, PhD, Regulatory Affairs, Merck & Company

Review of Flexeril OTC Development Program

Scott Korn, M.D. Clinical Research, Merck & Company

11:30 Questions from Advisory Committees

12:00 Lunch

1:00 Open Public Hearing

2:00 Charge to the Committee

Linda Katz, M.D., M.P.H., Deputy Director of OTC